

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellants:	Schechter et al.	Examiner:	Michael Peffley
Serial No.:	10/712,486	Group:	Art Unit 3739
Filed:	November 13, 2003	Dated:	April 11, 2008

For: **COMPRESSIBLE JAW CONFIGURATION WITH BIPOLAR RF
OUTPUT ELECTRODES FOR SOFT TISSUE FUSION**

Mail Stop: Appeal Brief - Patents
Honorable Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF

Sir:

This Reply Brief is in response to the Examiner's Answer mailed on February 20, 2008,
for the above-identified patent application.

I. STATUS OF CLAIMS

The status of the claims of this application is as follows:

- A) Claims 1-5, 7, 8, and 21-23 are pending;
- B) Claims 6, 9-20 have been withdrawn; and
- C) Claims 1-5, 7, 8, and 21-23 have been rejected and are under appeal.

II. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Appellants request review of the following outstanding grounds of rejection:

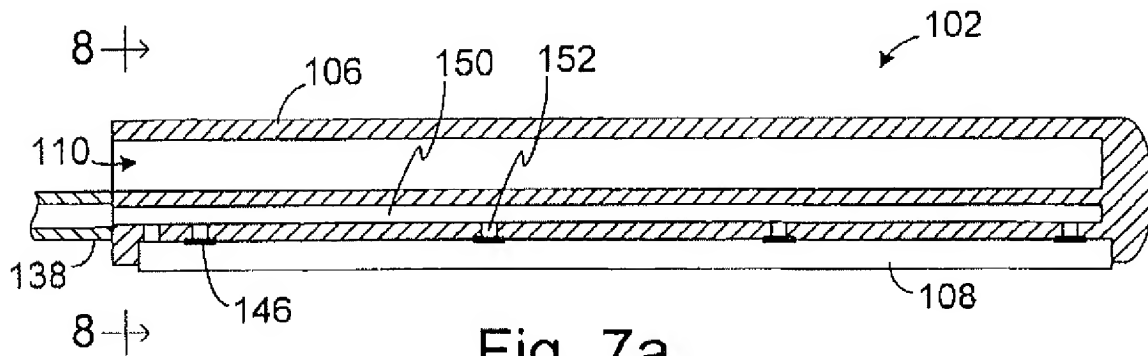
A) The rejection of Claims 1-5, 7-8 and 21-23 under 35 U.S.C. §103(a) over U.S. Patent No. 6,932,816 to Phan ("Phan") in view of U.S. Patent No. 6,086,586 to Hooven ("Hooven").

III. ARGUMENT

A) The rejection of Claims 1-5, 7-8 and 21-23 under 35 U.S.C. §103(a) over Phan in view of Hooven.

Claims 1-5, 7-8 and 21-23 stand rejected over U.S. Patent No. 6,932,816 to Phan ("Phan") in view of U.S. Patent No. 6,086,586 to Hooven ("Hooven"). Phan relates to an apparatus for converting a clamp into an electrophysiology device. Hooven discloses a bipolar tissue grasping apparatus and tissue welding method.

Independent Claims 1 and 21-23 each require a tissue or vessel sealing instrument, comprising, *inter alia*, "jaw members including an elastomeric material disposed on an inner facing tissue contacting surface thereof, each of the elastomeric materials including an electrode disposed therein." The Examiner relies on Phan to teach these features. Specifically, it is asserted that the base member (106) of Phan is disposed on an inner facing tissue contacting surface. Additionally, it is asserted that each base member (106) includes an electrode (108) therein. (See Figure 7a, 7b and 8 of Phan, reproduced below.)



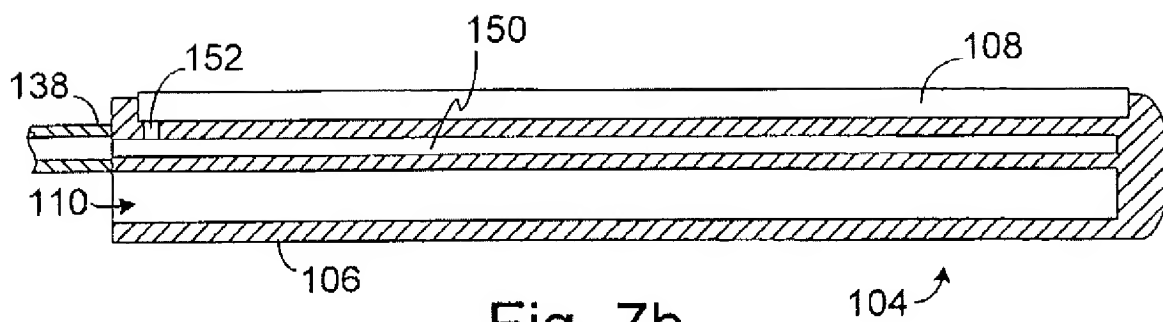


Fig. 7b

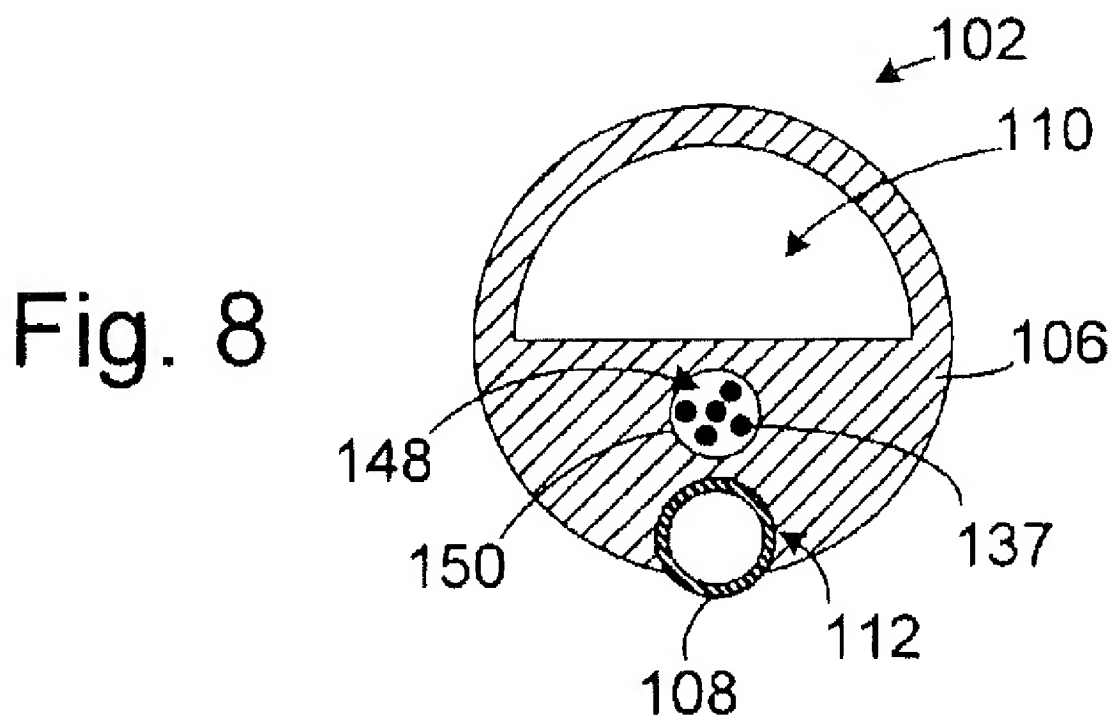


Fig. 8

In support of the Examiner's assertion that Phan's base member (106) is disposed on an inner facing tissue contacting surface, the "examiner maintains that when tissue is grasped, particularly at the closure pressure asserted by applicant, that tissue will inherently be squeezed and conform to the portion of the elastomeric base (106) immediately surrounding the electrode (108)." Thus, the Examiner concludes that the base member (106) of Phan is only disposed on

an inner facing tissue contacting surface upon compression of tissue. According to this interpretation of “tissue contacting surface,” any surface of any jaw member would have the ability to contact tissue (e.g., upon entry into a surgical site, during manipulation of the jaw members, during compression of tissue, and during removal of the jaw members from tissue) and would therefore be considered a “tissue contacting surface.” Such an interpretation is clearly overly broad and is thus improper.

In view of the language of Appellants’ claims that requires the elastomeric material to be “disposed on an inner facing tissue contacting surface,” and in view of the specification, which supports this claim language (see, for example, Fig. 3 of Appellants’ disclosure, reproduced below), Appellants maintain that Phan does not teach, disclose or suggest “jaw members including an elastomeric material disposed on an inner facing tissue contacting surface thereof,” as required by Claims 1 and 21-23.

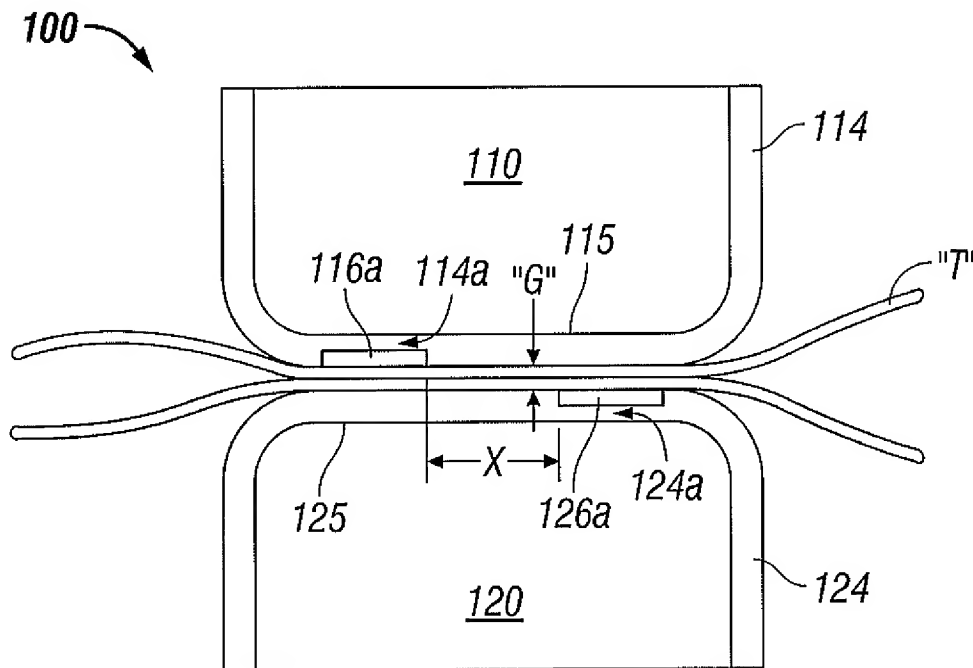


FIG. 3

Each of Claims 1 and 21-23 also require, *inter alia*, “each of the elastomeric materials including an electrode 108 disposed therein.” In the Examiner’s Answer, “the examiner maintains that the Phan base member (108) clearly surrounds the electrode, at least to the same extent that applicant’s base member surrounds the electrode as shown in the Figures.” Upon a detailed review of Figs. 7a, 7b and 8 of Phan, reproduced above, and Fig. 2 of Appellants’ disclosure, reproduced below, it is evident that the Examiner’s assertion is simply not accurate.

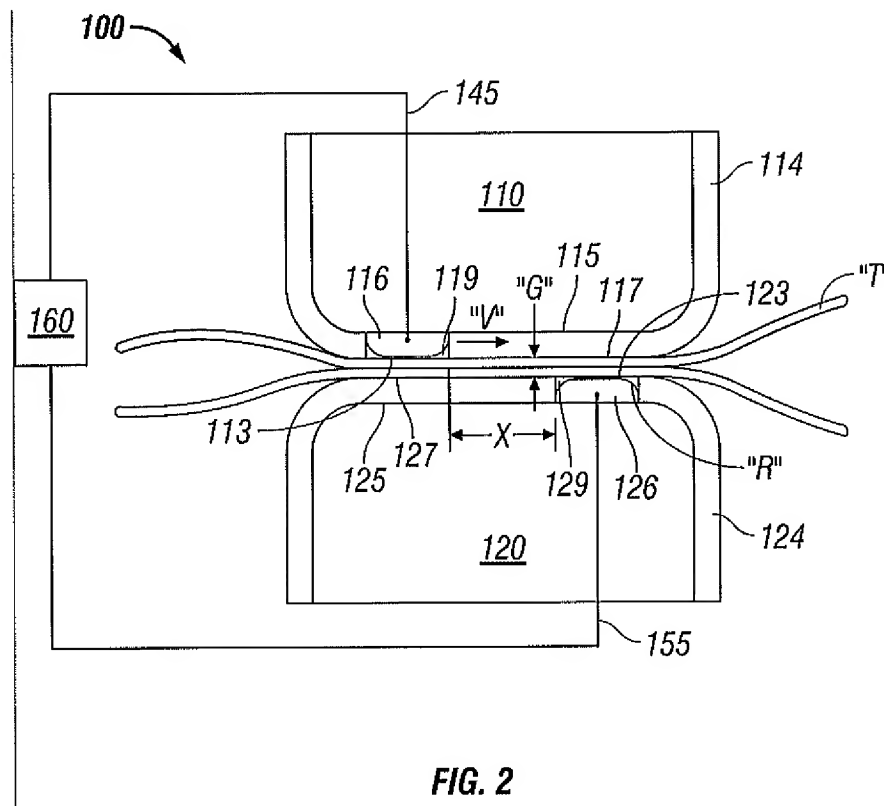


FIG. 2

Comparing the Figures of Phan and Appellants’ Figure 2 above, it is clear that Appellants’ electrodes (116, 126) are **within** pockets (119, 129) of shells (114, 124). Conversely, each of Phan’s electrodes extend from their respective base member and is therefore not **within** the base member. Accordingly, Appellants maintain that Phan does not teach, disclose or suggest “each of the elastomeric materials including an electrode 108 disposed therein,” as required by Claims 1 and 21-23.

Additionally, the Examiner relies on Hooven to teach jaw members having electrodes that are "offset a distance X relative to one another such that when the jaw members are closed about the tissue and when the electrodes are activated, electrosurgical energy flows through the tissue in a generally coplanar manner relative to the tissue contacting surfaces." It is further asserted that "it would have been obvious to one of ordinary skill in the art ... to have arranged electrodes on the device of Phan as claimed in view of the teaching of Hooven so that the flow of current between the electrodes naturally stops when coagulation is complete to prevent thermal damage due to over-coagulation outside the jaws."

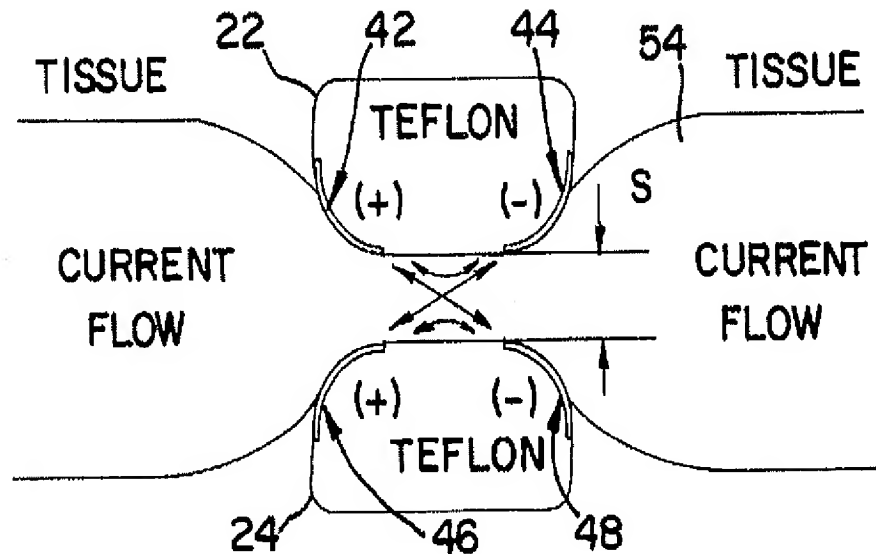
Appellants' disclosure relates to sealing tissue rather than coagulating tissue. As stated in the specification, "[i]n order to seal large vessels, two predominant mechanical parameters must be accurately controlled - the pressure applied to the vessel and the gap distance between the electrodes - both of which are affected by the thickness of the sealed vessel to be sealed. (See the first full paragraph of page 2.) With additional regard to sealing tissue, Appellants' disclosure states, *inter alia*:

[T]he distance "X" between adjacent electrodes 116 and 126 plays an important role in sealing vessels. Using computer simulations and histological evidence, it has been demonstrated that a non-uniform power-density exists due to the electrical and thermal properties of tissue. This results in a **non-uniform temperature distribution in which temperature is greater in a region centrally located between the electrodes**. Impedance in this central region can rise quickly creating an insulative barrier to further current flow across the tissue, **resulting in inadequate sealing** at the electrode edges... Thus, it has been determined that the distance "X", the distribution of energy across the seal and the relative size of the seal itself are all important parameters which must be properly considered during the sealing process. (Emphasis added.) (See paragraph bridging pages 19 and 20.)

Hooven relates to coagulating tissue rather than sealing tissue. Specifically, Hooven includes electrode pairs 42, 44 and 46, 48, with each pair including a positive electrode and a negative electrode. Upon activation, current flows between one positive electrode (e.g., 42) and

both negative electrodes (44 and 48), and vice versa. As shown in Fig. 6 of Hooven, reproduced below, this results in current flowing between the electrodes of opposite polarity (i.e., across a single jaw member and from a first jaw member diagonally across to the other jaw member).

FIG. 6



Thus, in direct contrast to Appellants' disclosure and as can be appreciated with regard to Fig. 6 of Hooven, reproduced above, the orientation of electrodes in Hooven results in a **non-uniform temperature distribution in which temperature is greater in a region centrally located between the electrodes**. In fact, this is the exact problem the Appellants have solved with regard to sealing tissue. Further, if it were asserted that the grasping apparatus of Hooven can be used to seal tissue, the impedance in the central region (i.e., in the middle of the current flow 'x') would rise quickly creating an insulative barrier, which would inhibit current flow across the tissue, thus **resulting in inadequate sealing** at the electrode edges.

Additionally, Hooven states, "the current is at its maximum density **between** the tissue contacting surfaces of the jaws" (emphasis added) (Column 4, lines 35-36 of Hooven).

Therefore, “electrosurgical energy” **does not flow** “through the tissue in a generally **coplanar** manner relative to the tissue contacting surfaces,” as opposed to the requirements of Claims 1 and 21-23.

Accordingly, Hooven does not teach, disclose or suggest teach jaw members having electrodes that are “offset a distance X relative to one another such that when the jaw members are closed about the tissue and when the electrodes are activated, electrosurgical energy flows through the tissue in a generally coplanar manner relative to the tissue contacting surfaces,” as required by Claims 1 and 21-23.

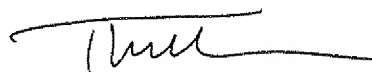
Thus, for at least the foregoing reasons, Phan and Hooven, taken alone or in combination, fail to disclose, teach or otherwise suggest the apparatus of independent Claims 1 or 21-23. Accordingly, withdrawal of this rejection is respectfully requested and Appellants earnestly seek allowance of Claims 1 and 21-23, and Claims 2-5 and 7-8, which depend from Claim 1.

CONCLUSION

In view of the foregoing remarks, Appellants respectfully submit that all of the claims now pending (and not withdrawn) in this application, namely, Claims 1-5, 7, 8, and 21-23 are in condition for allowance. Early and favorable reconsideration of this application is respectfully requested.

Please charge any deficiency as well as any other fee(s) which may become due under 37 C.F.R. §1.16 and/or 1.17 at any time during the pendency of this application, or credit any overpayment of such fee(s) to Deposit Account No. 21-0550. Also, in the event any extensions of time for responding are required for the pending application(s), please treat this paper as a petition to extend the time as required and charge Deposit Account No. 21-0550 therefor.

Respectfully submitted,



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IV. APPENDIX OF CLAIMS

1. A tissue or vessel sealing instrument, comprising:

a housing having a shaft attached thereto; and

an end effector assembly attached to a distal end of the shaft, the end effector assembly including first and second jaw members attached thereto made from a substantially rigid material, the jaw members being movable relative to one another from a first position for approximating tissue to at least one additional position for grasping tissue therebetween;

each of the jaw members including an elastomeric material disposed on an inner facing tissue contacting surface thereof, each of the elastomeric materials including an electrode disposed therein, the electrodes being offset a distance X relative to one another such that when the jaw members are closed about the tissue and when the electrodes are activated, electrosurgical energy flows through the tissue in a generally coplanar manner relative to the tissue contacting surfaces, the elastomeric material being adapted to compress or deflect about 0.001 inches to about 0.015 inches when the force used to close the jaw members is between about 40 psi to about 230 psi; and

wherein the substantially rigid material of the jaw members resists deformation when the force used to close the jaw members is between about 40 psi to about 230 psi.

2. The tissue or vessel sealing instrument of claim 1, wherein the elastomeric material is selected from the group consisting of at least one of the following materials: silicone, polyurethane, santoprene, nylon, syndiotactic polystyrene, Polybutylene Terephthalate (PBT), Polycarbonate (PC), Acrylonitrile Butadiene Styrene (ABS), Polyphthalamide (PPA), Polyimide, Polyethylene Terephthalate (PET), Polyamide-imide (PAI), Acrylic (PMMA), Polystyrene (PS

and HIPS), Polyether Sulfone (PES), Aliphatic Polyketone, Acetal (POM) Copolymer, Polyurethane (PU and TPU), Nylon with Polyphenylene-oxide dispersion and Acrylonitrile Styrene Acrylate.

3. The tissue or vessel sealing instrument of claim 1, wherein the offset distance X is in the range of about 0.005 inches to about 0.200 inches.

4. The tissue or vessel sealing instrument of claim 1, further comprising at least one sensor which provides information to a feedback circuit for regulating the electrosurgical energy through the tissue.

5. The tissue or vessel sealing instrument of claim 4, wherein the sensor measures at least one of tissue impedance, tissue temperature and tissue thickness.

6. (Withdrawn) The electrosurgical instrument of claim 1, wherein at least one of the jaw members includes means for regulating the distance X dependent upon tissue thickness or tissue type.

7. The tissue or vessel sealing instrument of claim 1, wherein at least one of the jaw members includes at least one electrode across the width thereof and the electrosurgical instrument includes means for selecting one of the electrodes for electrically opposing the electrode disposed on the other of the jaw members, wherein the means includes a sensor which measures at least one of tissue impedance, tissue temperature and tissue thickness.

8. The tissue or vessel sealing instrument of claim 1, wherein the elastomeric material has a comparative tracking index value of about 300 to about 600 volts.
9. (Withdrawn) The electrosurgical instrument of claim 1, wherein the electrodes are wire electrodes which project from the tissue contacting surfaces of the elastomeric material into contact with the tissue.
10. (Withdrawn) The electrosurgical instrument of claim 1, wherein the elastomeric material on each of the jaw members includes an electrode which is partially disposed therein.
11. (Withdrawn) The electrosurgical instrument of claim 10, wherein upon grasping of tissue between the jaw members, each of the electrodes deflect inwardly relative to the tissue contacting surfaces.
12. (Withdrawn) The electrosurgical instrument of claim 11, wherein the electrodes are recessed within the elastomeric material.
13. (Withdrawn) The electrosurgical instrument of claim 12, wherein the tissue contacting surface of each electrode is substantially crowned.
14. (Withdrawn) An electrosurgical instrument for sealing tissue, comprising:
 - a housing having a shaft attached thereto; and
 - an end effector assembly attached to a distal end of the shaft, the end effector assembly including first and second jaw members attached thereto, the jaw members

being movable relative to one another from a first position for approximating tissue to at least one additional position for grasping tissue therebetween;

each of the jaw members including an insulative material disposed on an inner facing tissue contacting surface thereof and an elastomeric material disposed between each jaw member and a respective insulative material, each of the insulative materials includes an electrode disposed therein, the electrodes being offset a distance X relative to one another such that when the jaw members are closed about the tissue and when the electrodes are activated, electrosurgical energy flows through the tissue in a generally coplanar manner relative to the tissue contacting surfaces.

15. (Withdrawn) The electrosurgical instrument of claim 14, wherein the offset distance X is in the range of about 0.005 inches to about 0.200 inches.

16. (Withdrawn) The electrosurgical instrument of claim 14, further comprising at least one sensor which provides information to a feedback circuit for regulating the electrosurgical energy through the tissue.

17. (Withdrawn) The electrosurgical instrument of claim 16, wherein the sensor measures at least one of tissue impedance, tissue temperature and tissue thickness.

18. (Withdrawn) The electrosurgical instrument of claim 14, wherein at least one of the jaw members includes a plurality of electrodes across the width thereof and the electrosurgical instrument includes means for selecting one of the plurality of electrodes for electrically opposing the electrode disposed on the other of the jaw members, wherein the means includes a

sensor which measures at least one of tissue impedance, tissue temperature and tissue thickness.

19. (Withdrawn) The electrosurgical instrument of claim 14, wherein the insulative material on each of the jaw members includes an electrode which is partially disposed therein.

20. (Withdrawn) The electrosurgical instrument of claim 19, wherein the electrodes are recessed within the insulative material.

21. A tissue or vessel sealing instrument, comprising:

a housing having a shaft attached thereto; and

an end effector assembly attached to a distal end of the shaft, the end effector assembly including first and second jaw members attached thereto made from a substantially rigid material, the jaw members being movable relative to one another from a first position for approximating tissue to at least one additional position for grasping tissue therebetween;

each of the jaw members including an elastomeric material disposed on an inner facing tissue contacting surface thereof, each of the elastomeric materials including an electrode disposed therein, the electrodes being offset a distance X relative to one another such that when the jaw members are closed about the tissue and when the electrodes are activated, electrosurgical energy flows through the tissue in a generally coplanar manner relative to the tissue contacting surfaces, wherein the elastomeric material is selected from the group consisting of at least one of the following materials: silicone, polyurethane, santoprene, nylon, syndiotactic polystyrene, Polybutylene Terephthalate (PBT), Polyphthalamide (PPA), Polyimide, Polyethylene Terephthalate (PET),

Polyamide-imide (PAI), Acrylic (PMMA), Polystyrene (PS and HIPS), Polyether Sulfone (PES), Aliphatic Polyketone, Acetal (POM) Copolymer, Polyurethane (PU and TPU), Nylon with Polyphenylene-oxide dispersion and Acrylonitrile Styrene Acrylate, the elastomeric material being adapted to compress or deflect about 0.001 inches to about 0.015 inches when the force used to close the jaw members is between about 40 psi to about 230 psi; and

wherein the substantially rigid material of the jaw members resists deformation when the force used to close the jaw members is between about 40 psi to about 230 psi.

22. A tissue or vessel sealing instrument, comprising:

a housing having a shaft attached thereto; and

an end effector assembly attached to a distal end of the shaft, the end effector assembly including first and second jaw members attached thereto made from a substantially rigid material, the jaw members being movable relative to one another from a first position for approximating tissue to at least one additional position for grasping tissue therebetween;

each of the jaw members including an elastomeric material disposed on an inner facing tissue contacting surface thereof, the elastomeric material being adapted to compress or deflect about 0.001 inches to about 0.015 inches when the force used to close the jaw members is between about 40 psi to about 230 psi, each of the elastomeric materials including an electrode disposed therein, the electrodes being offset a distance X relative to one another such that when the jaw members are closed about the tissue and when the electrodes are activated, electrosurgical energy flows through the tissue in a generally coplanar manner relative to the tissue contacting surfaces, wherein the offset

distance X is in the range of about 0.005 inches to about 0.200 inches; and

wherein the substantially rigid material of the jaw members resists deformation when the force used to close the jaw members is between about 40 psi to about 230 psi.

23. A tissue or vessel sealing instrument, comprising:

a housing having a shaft attached thereto; and

an end effector assembly attached to a distal end of the shaft, the end effector assembly including first and second jaw members attached thereto made from a substantially rigid material, the jaw members being movable relative to one another from a first position for approximating tissue to at least one additional position for grasping tissue therebetween;

each of the jaw members including an elastomeric material disposed on an inner facing tissue contacting surface thereof, each of the elastomeric materials including an electrode disposed therein, the electrodes being offset a distance X relative to one another such that when the jaw members are closed about the tissue and when the electrodes are activated, electrosurgical energy flows through the tissue in a generally coplanar manner relative to the tissue contacting surfaces, the distance X being variable depending on the thickness of the tissue between the jaw members, the elastomeric material being adapted to compress or deflect about 0.001 inches to about 0.015 inches when the force used to close the jaw members is between about 40 psi to about 230 psi; and

wherein the substantially rigid material of the jaw members resists deformation when the force used to close the jaw members is between about 40 psi to about 230 psi.